K073709

EPMedSystems

510(k) Summary

Summary preparation date: 12/28/07

1. Device Trade Name

Device Trade Name	Device Classification
ViewMate® System	II
This application describes a modification to the ViewMate® System's catheter called ViewFlex® PLUS.	

MAR 11 2008

2. Establishment Address and Registration

EP MedSystems Inc.
Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 USA

Larry Picciano
Telephone: 856-753-8533, x221
Fax: 856-753-8544
E-mail: lpicciano@epmedsystems.com

US Food and Drug Administration Establishment Registration No.: 2248049

3. Device Classification

Classification	Product Code	Device Classification Name	Regulation Number	Classification Number	Performance Standard(s)
Primary	IYN	System, Imaging, Pulsed Doppler, Ultrasonic	892.1550	II	None
Subsequent	ITX	Transducer, Ultrasonic	892.1570	II	None
Subsequent	IYO	System, Imaging, Pulsed Echo, Ultrasonic	892.1560	II	None

4. Predicate Devices / Technology

Product Description	510 (k) No.	Date
ViewMate® System	031066	10/17/03
ViewMate® System	071028	05/01/07

5. Labeling and Intended Use

The following draft labeling is contained within **Appendix 4**.

5.1. Product Labeling
5.2. Marketing Literature
5.3. Instructions for Use

6. Intended Use

The ViewMate® System is intended to be used to visualize cardiac structures and blood flow within the heart.

7. Indications for Use

The ViewMate® System is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart

Note: A copy of the original Diagnostic Ultrasound Indications for Use Form (K031066), which is not affected by this notification, is provided in **Appendix 5**.

8. Device Description

8.1. The purpose of this submission is to provide premarket notification of modifications to the mechanical design of the ViewFlex® catheter; the modified device will be marketed as ViewFlex® PLUS catheter (model VF-PM). The intended use and indications for use of the ViewFlex® catheter are not affected. No changes have been made to the ultrasound or electronics design of the catheter; the ultrasound transducer and its performance is not affected by the proposed changes. Similarly, no changes have been made to the ViewMate® or the ViewMate® II (PMS HD11 XE) console.

8.2. **Background of the ViewMate® System with the ViewFlex® Catheter:** The ViewFlex® ultrasound catheter in combination with the ViewMate® cardiac ultrasound imaging console was first cleared for US marketing on October 17, 2003 (K031066). Clearance to market a modification to the ViewFlex® catheter was received on May 1, 2007 (K071028). On August 18, 2006 EPMedSystems' ViewFlex® catheter was cleared for US marketing with Philips Medical Systems' (PMS) HD11 XE Ultrasound System (K062247). On January 9, 2007 EPMedSystems (the company) entered into a contractual agreement with PMS to market the HD11 XE under the EPMedSystems trade name ViewMate® II. As a US registered medical device distributor, re-packager and re-labeler, EPMedSystems has been distributing the ViewMate® II console. The company plans to continue distributing the ViewMate® II console for use with ViewFlex® catheters.

8.3. **General Description of the ViewMate® System with the ViewFlex® PLUS Catheter:** The ViewMate® cardiac ultrasound imaging system (K031066 and K071028) is intended to be used to visualize cardiac structures and blood flow within the heart; it is indicated for use in adult and adolescent pediatric patients. The ViewMate® system's intracardiac imaging capability is used by Electrophysiologists and Interventional Cardiologists in a number of ways, including but not limited to, assessing cardiac output, determining the size of the heart and

locating its structures, determining device location (e.g., electrophysiology catheters, pacing leads, PFO closure devices), positioning of devices, and visualizing blood flow through cardiac arteries. Cardiac electrophysiology (EP) procedures are complex diagnostic tests during which physicians look at electrical signals from the heart to determine if an abnormality (arrhythmia) exists. Use of the ViewMate® system in EP studies offers significant advantages in that it enables physicians to accurately place EP catheters and to identify physiologic and blood flow anomalies. Interventional Cardiologists have recently begun using ViewMate® to view structures and devices during interventional cardiac procedures as well.

8.4. The ViewMate® System is a portable, computerized, ultrasound imaging system used to display and capture intracardiac ultrasound images. The ViewMate® System illustrated in **Figure 1** is comprised of three components: ViewMate® console, patient isolation module and the ViewFlex® PLUS ultrasound catheter.

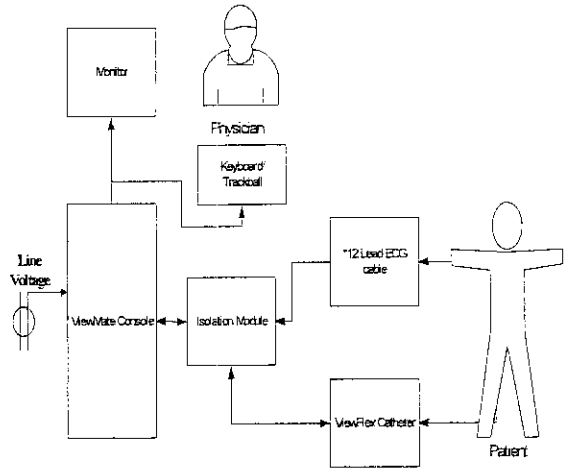

Figure 1: ViewMate® System

*Note: ViewMate II ECG connects directly to console with internal isolation.

8.5. The ViewMate® ultrasound console comprises a personal computer (PC), ultrasound imaging beam former and a digital frame grabber with storage. The system software is used to control imaging modes, image quality, image acquisition, storage, and retrieval of patient records (i.e., images, ECG, and notes). The system software enables multiple imaging modes: two dimensional (B mode and color Doppler) and time-motion mode (spectral Doppler/pulse wave Doppler and M Mode). Additional software functionality includes zoom, labeling, image storage, retrieval and review. ViewMate® may be used in interventional cardiology, specifically in the interventional EP laboratory.

8.6. **Description of ViewFlex® PLUS Catheter:** The ViewMate® connects with an ultrasound catheter called ViewFlex® PLUS that is inserted into the heart via intravascular access. The ViewFlex® PLUS catheter, illustrated in **Figure 2**, is a single use, temporary, intracardiac ultrasound catheter indicated for use in adult and adolescent pediatric patients. ViewFlex® PLUS mechanical properties are as follows: The catheter shaft is 9 French, approximately 90 cm long, constructed of radio-opaque tubing. The catheter offers bi-directional steerability that can be manipulated with one hand. A minimum of a 10 French introducer is

recommended for use with this catheter for insertion into the femoral or jugular veins. ViewFlex® PLUS imaging properties are as follows: The catheter consists of a 64-element linear phased array, wideband transducer with an imaging frequency range of 4.5 MHz to 8.5 MHz, user-selectable magnification, 86° viewing angle on the ViewMate® I system and a viewing angle of 90° on the ViewMate® II system.

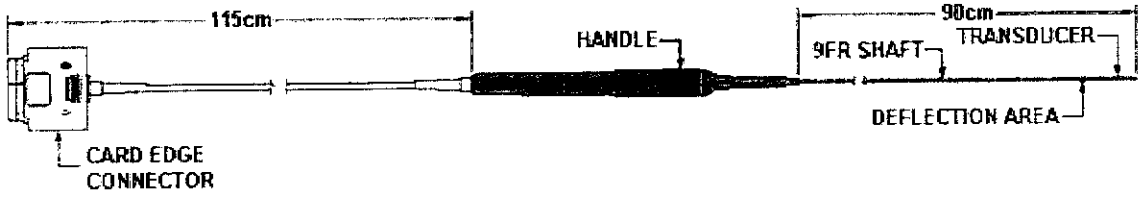

Figure 2: ViewFlex® PLUS Catheter

8.7. **Change Scope and Description:** The intent of this submission is to provide premarket notification of modifications to the mechanical design of the ViewFlex® catheter; the modified device will be marketed as ViewFlex® PLUS catheter (model VF-PM). The intended use and indications for use of the ViewFlex® catheter are not affected. No changes have been made to the ultrasound or electronics design of the catheter; the ultrasound transducer and its performance is not affected by the proposed changes. Similarly, no changes have been made to the ViewMate® or the ViewMate® II (PMS HD11 XE) console. The catheter modification is intended to satisfy the broadening range of ICE (IntraCardiac Echo) user needs that have been realized since the product's original release (K031066). Specifically, the modification increases the range of angulation (i.e., bending of the distal tip measured in degrees) and increases the stability (i.e., firmness) of the positioned catheter. In addition to meeting a broader range of user needs, these changes position the product more competitively in the market place. EPMedSystems employed design controls, including verification and validation in the design change process. The changes are detailed in **Appendix 6** and in the supporting documentation provided. The following table summarizes the changes.

Change #	Change Classification	Change Description	Reason
1	Finished product, external modification	Reduce usable length from 110cm to 90 cm	Extra 20cm is not used in right heart catheterizations. Competitive product is 90cm.
2	Finished product, external material change and performance change	Replace covering of distal transfer section with 35D PEBAX® with metal braiding	Extending the braiding to the transducer increases catheter stability
3	Finished product, internal material change	Replace steering wires with 0.003" x 0.010" stainless steel wire	Satisfy broadened user requirements - increase deflection range
4	Finished product, internal material change	Add one Teflon® tube over individual steering wires	Satisfy broadened user requirements - increase deflection range
5	Finished product, internal material change	Replace adhesive bonding shaft to the transducer with FDA 2 epoxy.	Increase production yield
6	Finished product, internal material change	Replace wire post (0.062" OD) pin with (0.220" OD) tube	Satisfy broadened user requirements - increase deflection range
7	Finished product, internal material change	Add Advanced Polymer heat shrink 140250 at proximal joint	Satisfy broadened user requirements - increase deflection range
8	Production process change	Eliminate gluing of transfer section cover, employ heat fusing and continuous braiding	Increase production yield
9	Performance change	Increased angulation from ±30° to ±120°	Satisfy broadened user requirements - increase deflection range

Table 1: ViewFlex® Catheter Change Summary

8.8. **Product Numbering Change Notice:** In an effort to make it easier for customers to order catheters and to clarify product identification, EPMedSystems is modifying the way it refers to its ViewFlex® catheters. This is strictly a nomenclature change. The company currently uses VF-01 to represent the ViewFlex® catheter model number. Moving forward EPMedSystems will refer to the ultrasound products as follows in **Table 2**.

Number Description	Former Number	New Number
Catheter Model Number[1]	VF-01	VF-PM
Ultrasonic *Transducer Model* Number[2]	204	PA 6.5/64
Catheter Part Number	VF-PA9F64E2DW[3,4]	09-2005[5]
Product Code[6]	VF-PA9F64E2DW[3,4]	NA[6]

Table 2: Product Identification Change

Notes:
(1) "Catheter" and "Transducer" are not used synonymously.
(2) "Transducer" model refers to the active ultrasonic element commonly referred to as a piezoelectric crystal contained within the catheter - there is no change to this component, it is the same as that first cleared under K031066.
(3) "W" indicates wire added as part of the redesign (K071028); this differentiates the product by design.
(4) Units of former design (K031066) may also be sold as VF-PA9F64E2D.
(5) Part number is redesigned to accommodate additional curve sizes as the product line expands (e.g., 09-2003 for size 3, 09-2005 for size 5, 09-2007 for size 7).
(6) The company will no longer refer to the VF-PM by a numeric product code; company's internal device identification will be the part number. Note, this product code is not the same as the three digit FDA alpha product code used for device description/classification.

End of document

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 11 2008

EP MedSystems, Inc.
c/o Mr. Larry Picciano
Director of Regulatory Systems
Cooper Run Executive Park
575 Route 73 North, Unit D
West Berlin, NJ 08091

Re: K073709
ViewMate® System with ViewFlex® PLUS Catheter
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II (two)
Product Code: IYN, IYO, ITX, OBJ
Dated: February 15, 2008
Received: February 19, 2008

Dear Mr. Picciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ViewMate® System, as described in your premarket notification:

ViewFlex® PLUS Catheter, Model VF-PM

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lisa E. Leveille at (240) 276-4095.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EPMedSystems

Cooper Run Executive Park
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West Berlin, New Jersey 08091
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Fax: (856)753-8544

Indications for Use

Device Name: ViewMate® System (K073709)

Indications for Use: The ViewMate® System is indicated for use in adult and adolescent pediatric patients to visualize cardiac structures and blood flow within the heart.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Division of Cardiovascular Devices
510(k) Number K073709

File: VF-PM Sp 510(k) Indcations for Use 122707

Re: K073709 Attachment: 4.2

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	**Mode** of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)		P	P	P		P				

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Catheter Model : ViewFlex® PLUS
Ultrasound Element : PA 6.5/64
Catheter Model Number : VF-PM
Catheter Part Number : 09-2005

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)